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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually, **Plaintiffs,** **v.** **ELI LILLY AND COMPANY,** **Defendant.**	§	CIVIL ACTION NUMBER CGC-07-463338 **COMPLAINT FOR DAMAGES** **[UNDER SEAL]**

Qui tam Plaintiff/Relator Jaydeen Vicente ("Plaintiff-Relator"), on behalf of the State of California and herself individually, for her Complaint against Defendant Eli Lilly and Company ("Lilly" or "Defendant Lilly") alleges based upon personal knowledge and relevant documents, as follows:

I. NATURE OF ACTION

1. This is an action to recover damages and civil penalties on behalf of the State of California arising from 1) intentionally false and/or fraudulent records caused to be presented and 2) statements and records caused to be made to get false claims paid by Defendant Lilly and/or its agents, employees and co-conspirators to California's Medicaid

Program, commonly known as Medi-Cal, in violation of the California False Claims Act, Cal. Govt. Code §12650 *et seq.*

2. The instant matter arises in principal part from Defendant Lilly's nationwide, coordinated deceptive off-label marketing and promotional practices for its potent atypical antipsychotic Zyprexa. Specifically, Lilly devised, and successfully implemented through its divisions of Zyprexa sales representatives, a marketing campaign calculated to increase physicians' off-label use of Zyprexa within the State of California to treat symptoms, mood disorders and patients within age demographics for which the drug has not received FDA approval, nor which has been supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information.

3. The conduct alleged herein shows a pattern of conduct designed to maximize profits at the California Medicaid Program's expense.

4. Lilly's Zyprexa sales representatives were among primary resources used by Lilly to dramatically increase Zyprexa sales for off-label uses to beneficiaries of California's Medicaid program.

5. Lilly organized its Zyprexa sales force into several divisions. One such division was a ***Long Term Care*** ("LTC") sales force consisting of 160 sales persons in 2000 to whom Lilly paid a generous salary and offered personal incentives such as bonus programs in exchange for the unlawful and deceitful off-label promotion of Zyprexa in the elderly demographic. Lilly's Zyprexa LTC sales representatives' sole objective was to promote the potent and expensive antipsychotic within the LTC market for a litany of unapproved and untested off-label medical uses for the explicit and illicit purpose of increasing market share and revenues derived from this coveted patient population – which the drug was not, and still is not, FDA-approved to treat.

6. Lilly provided extensive training and Zyprexa product support (including advertising materials and exaggerated and misleading pro-Zyprexa studies) to its "specialty" LTC sales force tailored to promoting Zyprexa's safety and efficacy to geriatric

healthcare providers (closed-end pharmacies, geriatric physicians and LTC facilities) through misleading, deceptive and wanton means. In furtherance of its Zyprexa sales scheme, Lilly also paid kickbacks masquerading as speaker fees, honoraria, unrestricted educational grants, entertainment and other in-kind forms. Lilly disbursed its valuable kickbacks with the understanding and specific intent that the geriatric healthcare providers to which they were paid would increase their usage and/or dosage of Zyprexa in elderly LTC facilities. Lilly engaged in this conduct purposefully, with the foreseeable impact of increasing Zyprexa off-label sales revenues derived in principal part from Medicaid programs all across the country, including Medi-Cal.

7. Lilly's illegal and zealous off-label over promotion of Zyprexa was calculated to increase sales of Zyprexa in the elderly population for dementia symptoms, agitation, insomnia and many other generic symptoms with reckless disregard for the safety of the elderly patients prescribed the drug for such untested and unapproved uses which Lilly targeted in its off-label marketing campaign.

8. Plaintiff-Relator has personal knowledge that Lilly engaged in the Zyprexa off-label promotional effort in Long Term Care ("LTC") facilities and in primary care physicians' offices in the State of California as well as nationwide, as she was employed by Lilly as a LTC sales representative in the Northern California region.

9. Lilly's illegal Zyprexa marketing campaign was calculated to, and did, cause billions of dollars of Zyprexa to be prescribed off-label to vulnerable, elderly long term care nursing home residents and adults (who at most were depressed or presented with other mood-related symptoms or illnesses) since Lilly's drug was released on the prescription drug market in 1996. These expensive prescription purchases were funded, in whole or in part, principally by government-funded healthcare programs including Medi-Cal.

10. Lilly's off-label LTC Zyprexa scheme succeeded. Lilly's LTC sales force was the most successful of all Lilly's Zyprexa sales divisions. Specifically, Plaintiff-Relator gained personal knowledge from Lilly corporate employees during Lilly's regional and national sales conferences and from the sales data Lilly made available to her, that the

Zyprexa revenues generated per LTC sales representative far exceeded the Zyprexa revenues generated per sales representative in any of its other Zyprexa sales division.

11. The purchases of the billions of dollars of dangerous, potent off-label Zyprexa prescriptions in California were funded in principle part by and through the, *inter alia*, Medi-Cal program. The State of California would not have funded millions of dollars of Zyprexa purchases since the drug's launch in 1996 but for Lilly's unlawful, intentionally deceitful and aggressive marketing tactics alleged herein.

12. Lilly's conduct endangered the health of Medi-Cal beneficiaries by placing them at great risk of harm of developing serious, irreversible and even life-threatening side effects that were known to Lilly at all times relevant to this Complaint, but which Lilly intentionally concealed to protect its windfall of billions of dollars of annual Zyprexa sales revenues.

13. Hundreds of thousands of Medi-Cal beneficiaries have now and continue to fall victim to serious, irreversible diseases and or potentially life threatening medical conditions including diabetes and hyperglycemia, in addition to the substantially increased risk of death for certain patients, especially elderly patients with dementia, as a direct and proximate cause of Lilly's illegal and capricious Zyprexa marketing tactics.

14. The California False Claims Act (Cal. Gov. Code §§ 12650 et seq.) permits any person discovering a fraud perpetrated against the State of California to bring an action for herself and for the State of California and to share in any recovery. Plaintiff-Relator commences this *qui tam* action individually and on behalf of the State of California to recover treble damages and civil penalties under the California False Claims California False Claims Act, Cal. Gov. Code §§ 12650 et seq.

15. Although unfortunately, California's False Claims Act does not provide for a recovery of the exorbitant medical costs to treat the diseases and afflictions Lilly knew Zyprexa would cause, Plaintiff-Relator, on behalf of the State of California, seeks redress against Lilly under the California False Claims Act for each of the hundreds of thousands false claims for reimbursement for the prescription cost of Zyprexa Lilly intentionally and

willfully caused to be submitted to the Medi-Cal program.

II. PARTIES

16. Plaintiff-Relator brings this action on behalf the State of California to remedy the millions of dollars its Medicaid program has been fraudulently induced to pay as a result of false Zyprexa reimbursement claims submitted by, and caused to be submitted by, Defendant Lilly. The State of California and Plaintiff-Relator Vicente will be collectively referred to as "Plaintiffs."

17. Plaintiff-Relator Vicente is a citizen of the United States and resident of the State of California. She resides at 7 Castle Hill Court, Vallejo, CA, 94591. Plaintiff-Relator Vicente was employed by Lilly for three years beginning in February 2000 as a Long Term Care Pharmaceutical Representative in the State of California. In this capacity, Lilly trained, paid and directed Plaintiff-Relator to promote Zyprexa off-label to treat elderly LTC skilled nursing facility residents in Northern California. Lilly offered Zyprexa selling incentives to Plaintiff-Relator by structuring a bonus program available to her based upon sales revenues of Zyprexa generated in her territory from LTC sales.

18. Defendant Eli Lilly and Company is an Indiana corporation and has its principle place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. At all times relevant hereto, Lilly was engaged in the business of licensing, manufacturing, distributing, promoting and/or selling, either directly or indirectly, the pharmaceutical prescription drug Zyprexa throughout the State of California and the United States, through its third party agents and/or employees, including its LTC sales force and its primary care physician sales divisions.

III. FILING UNDER SEAL

19. In accordance with California False Claims Act, Cal. Gov. Code §12652(c)(2) and California Rules of Court, Rule 2.570, this complaint is filed *in camera* and will remain under seal and will not be served on the Defendant Lilly until the Court so orders. A copy of the complaint and written disclosure of substantially all material evidence and information the Plaintiff possesses have been served on the State of California

pursuant to California False Claims Act, Cal. Gov. Code §12652(c)(3).

IV. ORIGINAL SOURCE

20. Through her employment as Lilly "specialty" LTC sales representative assigned to the Northern California region, Plaintiff-Relator Vicente was trained and employed by Lilly to promote Zyprexa for off-label uses, specifically, for use in the elderly LTC demographic, as is alleged with particularity *infra*, Plaintiff-Relator acquired a wealth of direct, independent and non-public knowledge of Lilly's unlawful acts described in this Complaint.

21. Plaintiff-Relator gained personal knowledge of Lilly's kickback payments to physicians made for the purpose, and with the intent to, induce those physicians (both geriatric physicians and PCPs) to prescribe Zyprexa to his or her Medicaid beneficiary patients.

22. Plaintiff-Relator has personal knowledge of Lilly's corporate endorsement of this unlawful national off-label Zyprexa marketing scheme for the LTC market as well as other markets including primary care and also has personal knowledge of the specific Lilly corporate personnel responsible for implementing Zyprexa's off-label marketing.

23. Accordingly, Plaintiff-Relator is an "original source" of the non-public information alleged in this Complaint within the meaning of California False Claims Act, Cal. Gov. Code §12652(d)(3)(A) and (B), Plaintiff-Relator is concurrently providing to the State Attorney General a disclosure statement summarizing and supported by known material evidence in accordance with the provisions of California False Claims Act, Cal. Gov. Code §12652(c)(3).

V. JURISDICTION

24. This Court has jurisdiction over the subject matter of this civil action. The State of California is a named plaintiff.

25. This Court has jurisdiction over Defendant Lilly because the drug company can be found in, is authorized to transact business in, and is now transacting business in the State of California.

VI. THE MEDI-CAL AND MEDICARE PART D PRESCRIPTION DRUG REIMBURSEMENT BENEFIT

A. The Medi-Cal Program

29. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded by Medicaid up until January 1, 2006 was funding for the prescription drug needs of the Medicaid program beneficiaries.

30. At all times relevant to the Complaint, in most states, Medicaid was an open-ended federal-state matching program. The federal government contributes a fixed percentage of the state's Medicaid costs each year; however, the exact percentage the federal government contributes varies year to year using a formula that takes into account the state's per capita income relative to the national per capita income.

31. The percentage of state contribution the funding of prescription drug purchases, and all other covered Medicaid health benefits, typically amounted to at least 40% at all times relevant to the complaint.

B. The Medicare Part D Program

32. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States.

33. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

34. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

35. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

36. Pursuant to the Medicare Part D Program, states, including the Plaintiff State of California provide funding for the purchases of beneficiaries of that program's prescription drugs through what is commonly referred to as "claw back" provisions.

C. Reimbursement Limits on Off-Label Drug Prescriptions

37. Although Medi-Cal is administered by the State of California, Medi-Cal adheres to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal and state governments will pay for Medicaid programs.

38. The Medicaid program includes individualized provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, the eligibility of various drugs for federal financial participation ("FFP"), price controls on prescription drugs and drug manufacturer rebate agreements.

39. According to the Social Security Act, the State of California is entitled to FFP for reimbursement of pharmaceuticals for covered patient drugs. 42 U.S.C.A. §1396r-8. The definition of a "covered outpatient drug" is limited to those drug prescribed to treat medically excepted indications. 42 U.S.C.A. 1396(k)(3). A medically accepted indication is any use approved by the FDA, or supported by one of the three specifically identified compendia. *Id.* (k)(6). The compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information and the Drugdex

Information System. *Id.* at (g)(1)(b)(i).

40. By way of example, under the Florida Medicaid Program the determination of whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. 1396r-8, Chapter 465 F.S., and the Florida Medicaid Prescribed Drug Services Provider Handbook.

41. In addition to the statutory authority granted by 42 U.S.C. 1396r-8 allowing state Medicaid programs to exclude or otherwise restrict coverage of outpatient prescription drugs, pursuant to the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook to be reimbursed by Medicaid, a drug must be medically necessary and prescribed for medically accepted indications and dosages found in the (A) drug labeling ("labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article), the (B) American Hospital Formulary Service Drug Information, the (C) United States Pharmacopeia-Drug Information or the (D) DRUGDEX Information System.

42. Lilly knew or should have known the Medicaid regulations governing prescription drug reimbursement.

42. Whether the use of a drug is medically necessary was material to Medicaid's decision to reimburse for prescription. Consequently, the government would have denied reimbursement for claims made for prescriptions of Zyprexa if it had known the purpose for which the drug had been prescribed was medically unnecessary.

43. Use of Zyprexa, for example, for dementia, or for anxiety or depression in the elderly is not supported by the compendia as medically safe and effective, and therefore should not have been covered by the State of California's Medicaid programs, yet nonetheless, Lilly recklessly has promoted Zyprexa for those and other unauthorized, untested and unproven uses through the methods alleged in this Complaint.

44. Lilly expected and intended its unlawful Zyprexa promotional efforts to cause claims for reimbursement to be submitted to, *inter alia*, Medi-Cal. Lilly designed and implemented its aggressive off-label Zyprexa promotional tactics with the intent to

influence the prescribing choices of long-term care and primary care physicians who treat Medi-Cal beneficiaries. The intended and foreseeable effect Lilly's avaricious scheme was that the Medi-Cal would fund the cost of treatment with Zyprexa through its reimbursement claims system and accordingly, in turn, Lilly would directly and substantially increase its Zyprexa revenue stream at *inter alia* Medicaid expense.

45. Until recently, the State of California was unaware of the unlawful manner in which Lilly promoted Zyprexa off-label within the state and nationally.

46. Under the California False Claims Act, it is unlawful for any "person," as defined by the statute, to submit a false or fraudulent claim to Medicare and Medicaid. The act of submitting a false claim includes by causing another to submit a false claim as well as soliciting, receiving, offering or paying any kickback, bribe or rebate in connection with a Medicaid claim. Cal. Govt. Code §12651.

47. The California False Claims Act provides for penalties of up to $10,000.00 for each violation of the foregoing provisions.

48. Lilly has caused false claims to be submitted to Medicaid for reimbursement through its promotional efforts in violation of the California False Claims Act.

49. In summary, throughout the country and in the State of California, Lilly aggressively and intentionally marketed Zyprexa for non-indicated uses and non-medically necessary uses including for the treatment of general mood and behavior disorders, attention deficit disorder, the attention deficit hyperactivity disorder, depression *not* associated with psychosis, sleeplessness, autism, Alzheimer's, dementia and aggression and agitation associated with dementia and Alzheimer's. Further, Lilly has intentionally misrepresented to prescribers who treat Medicaid participants that Zyprexa is safer than less expensive, generic antipsychotics such as Haldol which costs pennies per day rather than the extraordinary expense of Zyprexa.

50. By and through this and other conduct, Lilly caused tens of thousands of prescription reimbursement claims for Zyprexa prescribed for medically unnecessary and non-indicated uses to be submitted to the Medicaid/Medicare programs for reimbursement.

However, the prescription drug reimbursement claims for off-label uses of Zyprexa Lilly caused to be submitted to the Government as a direct result of its unlawfully off-label promotion campaign were not eligible for reimbursement from Medicaid, the VA or CHAMPUS/Tricare (and Medicare Part D, when it came into effect on January 2006) because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute.

51. Lilly engaged in its national Zyprexa promotional blitz with the knowledge that the majority of Zyprexa prescriptions written as a result thereof are reimbursed by government-funded health programs such as Medicaid, as well as with the knowledge that such prescriptions were for non-medically accepted indications and non-medically necessary uses of Zyprexa that fall outside the coverage of Medicaid.

VII. BACKGROUND

A. FDA Regulation of Drug Companies and their Marketing Practices

52. As detailed below, Lilly's conduct also materially and wantonly violated the FDA's regulations and federal law governing off-label marketing and truthful labeling and promotion of prescription drugs. Lilly engaged in this profit-driven misconduct for the purpose of deceiving physicians with their false and fraudulent off-label marketing message to cause the submission of false claims for Zyprexa to the State of California.

1) The FDA's Regulation of Promotional Activities of Drug Manufacturers

53. A prescription drug's product labeling contains the drug's indication. Drug product labeling broadly defined by federal regulation, including 21 C.F.R. § 202.1(k)(2), which provides that drug manufacturers' marketing and promotional materials for their drugs aimed at physicians, *i.e.*, all brochures, handouts, detail aids, slide shows or other such promotional materials, are also defined as "product labeling" and are stringently regulated as such. By law, representations made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any failure to

fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

54. Pharmaceutical promotional materials and presentations lacking in fair balance or that are otherwise false or misleading, violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drugs reference "off-label" uses or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated or are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

55. "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (*e.g.* treating a child with the drug when the drug is approved to treat adults).

56. Lilly materially violated these clear-cut labeling and misbranding regulations to illegally increase sales of its blockbuster drug in the off-label elderly market by and through its marketing and promotional efforts of its LTC sales force in direct-to-physician marketing.

57. Lilly, unable to control and bolster Zyprexa revenues by directly submitting prescription drug reimbursement claims to Medicaid and Medicare, instead launched a campaign intended to increase Government-funded off-label purchases of Zyprexa by defrauding LTC physicians, pediatric physicians and primary care physicians ("PCPs") to prescribe Zyprexa. The natural, intended and foreseeable consequence of such unlawful, premeditated conduct caused physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

58. Each such claim Lilly knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to get claims for Zyprexa paid, constitutes a false claim for which Lilly is accountable under the California False Claims Act.

2) Federal Law Prohibits Off-Label Marketing To Protect the Health and Safety of Patients

59. Off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law because of its inherent dangers. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

60. Under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose (notably, however, Lilly's creation of a LTC sales division directly evidences Lilly introduced Zyprexa into interstate commerce with the specific intent that it be used for off-label purposes, *i.e.*, to treat vague cross-over symptoms in the elderly, as pleaded with specificity herein), and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

61. Physicians are not prohibited from prescribing an FDA-approved drug "off-label"; however, pharmaceutical promotional activities and marketing materials and presentations are false or misleading in violation the Food Drug and Cosmetics Act and regulations promulgated hereunder if they advertise "off-label" uses of a drug, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated.

62. When pharmaceutical companies illegally encourage off-label uses for their drugs, the number of prescriptions rises, thereby causing Medicaid and other programs to pay out more for prescriptions that are not eligible for payment. Lilly intended for its "off-label" promotional campaign to improperly increase the submissions of off-label Zyprexa

prescriptions, including such prescriptions reimbursed by the Medicare and Medicaid programs.

63. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

64. Any claim submitted for a drug when the drug was prescribed for an off-label use not only violates Medicare payment rules but also files a fraudulent claim under the False Claims Act. 31 U.S.C. §3802. Claims for Zyprexa prescriptions induced to be written and submitted by Medicaid/Medicare participating pharmacy benefits providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign has caused the State of California to suffer substantial economic harm.

B. Zyprexa's Limited Indicated Uses

65. In September of 1996, the FDA approved Zyprexa tablets for use in the treatment of adults of schizophrenia at target doses of 10 mg. per day. In 2001, the Zyprexa tablets were approved for treatment of adults suffering from acute manic episodes associated with bipolar I disorder at dosages of up to 20 mg. per day. In July of 2003, Zyprexa tablets were approved for the short-term treatment of adults suffering from acute manic episodes associated with bipolar I disorder, in combination with lithium or **Depakote (valproic acid)**, with a recommended doses of 10 to 20 mg. per day. In January of 2004, Zyprexa tablets were approved for long-term treatment of adults diagnosed with bipolar disorder in doses of up to 20 mg. per day.

66. In 2001, Lilly launched ZYPREXA Zydis, an orally disintegrating tablet form of Zyprexa. ZYPREXA Zydis was specifically identified as an "opportunity" in Lilly's 2001 LTC Business Plan.

67. ZYPREXA Zydis tablets were made available in 4 strengths: 5 mg, 10 mg, 15 mg, and 20 mg. ZYPREXA Zydis has essentially the same efficacy and safety profile as

regular ZYPREXA tablets, and is indicated by the FDA for the same conditions: schizophrenia, maintenance of treatment response in schizophrenia and acute mania associated with bipolar I disorder in patients experiencing a manic or mixed episode.

68. The purpose of the introduction of the new disintegrating tablet form of Zyprexa was for "Convenient Administration." Because this Zyprexa tablet is formulated to easily dissolve within seconds of being placed in the patient's mouth, the drug was touted by Lilly as an important additional option for treating elderly patients, who may have difficulty swallowing a regular tablet form. In addition, Lilly promoted Zydis as providing a convenient alternative to liquid formulations of other drugs, and because absorption is not affected by food, it can be taken without regard to meals or drinking liquids, although, if patients wanted to drink something along with the medication, they may, but it is not necessary.

69. Lilly provided Plaintiff-Relator with training materials to assist in the promotion of ZYPREXA Zydis in the LTC demographic.

I) Medical Compendia Limited Supported Uses of Zyprexa

70. The HFS, the United States Pharmacopeia–Drug Information and the DRUGDEX information system support the use of Zyprexa in adult (not geriatric) schizophrenic or bipolar patients only. The uses supported by the three compendia and the FDA approved labeling are collectively defined as Zyprexa's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. § 1396r-8. Neither the compendia cited above nor the FDA-approved labeling supports any use of Zyprexa by the elderly, by children or for treatment of adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

VIII. PLAINTIFF-RELATOR'S PERSONAL KNOWLEDGE OF LILLY'S SUCCESSFUL, NATIONAL OFF-LABEL ZYPREXA MARKETING AND PROMOTIONAL PRACTICES

71. In or about February 2001, Lilly hired Plaintiff-Relator as a Long Term Care ("LTC"), Specialty, Pharmaceutical Representative.

72. Plaintiff-Relator's hiring came on the heels of one of Lilly's expansions of its LTC sales division. Since Lilly established the LTC sales division, which upon information and belief occurred simultaneously with the drug's launch in 1996, Lilly periodically expanded the LTC sales division.

73. At the time Lilly hired Plaintiff-Relator, there were 160 LTC Zyprexa sales representatives whose territories spanned the United States. See Exhibit "A." Initially, there were only 15 LTC sales representatives. In August 1999 that number was expanded to 59. In March 2000, concomitant with Zyprexa gaining sales momentum in the LTC market, Lilly nearly tripled its LTC sales force to 160. *Id.* Lilly continued to increase the size of its LTC sales force thereafter.

74. Lilly's stated purpose for expanding the LTC division was to, *inter alia*, maximize Zyprexa sales to patients who receive their medications *via* a LTC pharmacy. Indeed, Lilly even disseminated materials to LTC sales representatives overtly referring to the "Golden Opportunity in LTC Care" and the data that supported the vast potential for Zyprexa sales in this off-label market.

75. Lilly maintained a Zyprexa LTC sales division to fulfill one purpose - to aggressively promote Zyprexa on behalf of Lilly to LTC facilities that care exclusively for the elderly, despite the lack of any clinical trials or FDA approval for the use of Zyprexa in the elderly. Plaintiff-Relator gained personal knowledge of these facts during Lilly employment and has evidence substantiating these facts in the Lilly documents she retained from her Lilly employment, some of which are attached hereto as Exhibits. As alleged herein and in the expanded discussion of Lilly and its off-label promotion of Zyprexa in section IX, Lilly trained its LTC sales force to maximize Zyprexa's LTC care revenues.

76. For the duration of her employment with Lilly, Plaintiff-Relator's territory encompassed the LTC market for parts of Northern California, which she covered alone, and the scope of her employment was to promote, market and generate increased revenues from sales of Zyprexa prescriptions written to elderly LTC nursing home residents. Plaintiff-Relator detailed the Stockton Territory within the Sacramento District which

encompassed Modesto, Stockton, Lodi, Mantica, Oakdale, Ripon and the surrounding regions.

77. Plaintiff-Relator was required by Lilly to participate in and to graduate from a rigorous 4 week training course at Lilly's corporate headquarters in Indianapolis, Indiana.

78. There were 17 "new hire" LTC sales representative trainees from all over the United States in Plaintiff-Relator's training class. The LTC sales division was uniform throughout the country. All LTC sales representatives received uniform training, they all received the same Zyprexa marketing materials (of course all geared to selling Zyprexa to elderly patients) and all LTC sales representatives market Zyprexa in the LTC demographic in essentially the same manner, no matter which state and which territory.

79. The first two weeks of training focused on Zyprexa. The training topics included an "introduction" to the drug and what it does, the fundamentals about Zyprexa's competitor drugs and training about why Zyprexa is comparatively superior. LTC trainees were also given studies about Zyprexa, Zyprexa's competitors, Zyprexa's effectiveness compared to placebo and/or other atypicals and other similar studies that trainees were required to memorize. The purpose of memorizing these studies was for the Lilly LTC trainees to cite to and explain in detail these Zyprexa-supporting studies during sales calls on LTC physicians. Plaintiff-Relator was given Lilly training materials in connection with her training and was continuously tested throughout her training to monitor her progress.

80. The second two weeks of the training period focused entirely on how to sell Zyprexa to elderly patients in LTC skilled nursing facilities. In reality, this aspect of Lilly's training was a study in how to successfully market Zyprexa and induce physicians to prescribe Zyprexa to elderly patients to treat symptoms such as agitation, irritability, dementia and the like, all of which constitutes illegal off-label marketing.

81. Among other things, Plaintiff-Relator received extensive training from Lilly corporate training officials on subjects such as how to talk about the drug's efficacy in the treatment of Alzheimer's patients, how to induce physicians to ask "unsolicited" questions about Zyprexa off-label uses and to focus the marketing message on symptoms and

behaviors and Zyprexa's superior efficacy in "Restoring Calm," and that "nothing calms like Zyprexa." The sales materials discussed below carry forward this "Calming" selling message.

82. Lilly reinforced this training by providing mandatory role playing sessions designed to replicate what the LTC sales person would experience in the field when calling on LTC physicians.

83. Among other things, Lilly LTC salespersons including Plaintiff-Relator, engaged in role playing exercises that emulated physician sales calls. Lilly made it a prerequisite to "graduation" from Lilly's initial rigorous 4 month training for each LTC sales representative to receive a passing grade on a *videotaped* role-playing session designed to simulate "real life" marketing calls with LTC physicians.

84. Since Zyprexa has not been approved by the FDA to treat the elderly, Lilly trained its LTC sales persons (through such exercises as role playing) to discuss Zyprexa's efficacy and safety in treating generic symptoms known by Lilly to be commonplace in elderly LTC patients. The primary symptoms LTC sales representatives were trained to focus on were hostility and aggression, and to highlight Zyprexa as the drug of choice to "restore calm" in such agitated patients.

85. Notably, Plaintiff-Relator received scant training on schizophrenia and bi-polar disorders during the four weeks if her comprehensive LTC sales training. Instead, the majority of the training involved geriatric data and information. Lilly's focus on geriatrics over Zyprexa's indicated uses evidences Lilly's illegitimate purpose in maintaining a LTC sales division and reveals its focus and intent to achieve blockbuster off-label sales of Zyprexa. The calculated sales and marketing tactics demonstrate Lilly's conscious aforethought to off-label marketing.

86. Plaintiff-Relator, having worked in the pharmaceutical sales prior to Lilly, vocally questioned her Lilly trainers about the legality of the marketing practices being taught, specifically, she questioned the off-label nature of the Zyprexa marketing campaign promoting Zyprexa's safety and superior efficacy for geriatrics to LTC physicians, nursing

home employees and LTC pharmacies. Plaintiff-Relator was assured that by following Lilly's training on how to deliver the LTC Zyprexa message, off-label regulations would not be violated.

87. The role-playing seminars were not limited to LTC training. Rather, mandatory role-playing occurred at every Lilly sales meeting so sales representatives could "brush up" and hone their skills in delivering the misleading, deceptive and illegal Zyprexa off-label marketing tactics.

88. In addition to communicating such practices during frequent regional and district sales conferences, Lilly engrained its off-label marketing message during once or twice annual national sales meetings. During national sales meetings, specific gatherings, seminars, and training sessions were held solely for the Lilly LTC sales representatives.

89. As is detailed below, once Plaintiff-Relator graduated from training, she was continuously given Zyprexa marketing materials, such as studies, LTC implementation guides and "detail aids" tailored to selling Zyprexa in the geriatric market. Lilly's Zyprexa sales materials were the creation of the Zyprexa Brand Team, the division within Lilly responsible for developing the marketing and promotional selling message for Zyprexa in the United States.

90. Plaintiff-Relator also occasionally received promotional materials distributed by her Lilly manager, Dan Tubridy ("Tubridy"). One egregious example of such materials was a one-page sheet containing 2 form letters (one for Zyprexa and one for Zyprexa Zydis) with "fill in the blanks" to personalize the message to client-target physician and his or her geriatric patients Zyprexa doses and times of administration. See Exhibit "B." The letter's purpose was to suggest to the physician that his or her patients' Zyprexa dosage should be increased to reduce "nursing time and effort." Tubridy instructed Plaintiff-Relator to pass out this form letter to her target-physicians to induce an increase in Zyprexa dosage, which translated directly to increased Zyprexa sales revenues, by promoting Zyprexa's known side effect of somnolence. Promotion of Zyprexa as a chemical restraint for difficult, agitated elderly patients was not only illegal unsolicited off-label marketing, but also a wanton

derogation of patients' fundamental human rights.

91. Lilly's myopic focus and goal of driving Zyprexa off-label sales is evidenced by the convoluted manner in which LTC sales representatives' performance was evaluated. Job performance hinged entirely upon each LTC representatives *total sales revenues* generated by LTC Zyprexa purchases in her Northern California territory. Lilly's tunnel vision focus on salespersons profits, rather than number of prescriptions written evidences the avaricious nature of Lilly's illegal marketing pursuit, as it shows salespersons were expected not only to increase market share, but to increase dosages and/or frequency to rive up profits.

92. Plaintiff-Relator was continuously employed as a Lilly LTC sales representative for three years until on or about June 2003. At that time, she voluntarily resigned from her employment to accept a higher-paying pharmaceutical sales representative position with another pharmaceutical company. Plaintiff-Relator began pursing a career change while still a Lilly employee after Lilly executives rebuffed her attempts to rectify the unethical and illegal Zyprexa sales practices implemented and mandated by her Lilly Supervisor, Dan Tubridy.

93. Indeed, prior to leaving Lilly's employ, Plaintiff-Relator submitted to Lilly corporate a 3 page summary documenting all of Tubridy's illegal and unethical conduct. Exhibit "C." Lilly's rebuffed Plaintiff-Relator's attempt to right the wrongs of her manager, simply giving Tubridy a meaningless "warning," which was tantamount to a corporate endorsement of Tubridy's illegal, but successful Zyprexa sales methods. Soon thereafter, Plaintiff-Relator began seeking employment with another pharmaceutical company.

IX. ADDITIONAL FACTUAL BASIS OF LILLY'S ILLEGAL OFF-LABEL MARKETING OF ZYPREXA FOR ELDERLY OFF-LABEL USES AND TO PRIMARY CARE PHYSICIANS FOR OFF-LABEL USE TO TREAT NON-SCHIZOPHRENIC OR BIPOLAR ADULTS

94. As alleged supra in § VII B, Zyprexa is indicated to treat an exceptionally small subset of the United States population. Indeed, less than 7% of the United States'

adult population has been diagnosed with one of the rare mental illness for which Zyprexa is indicated for the treatment of symptoms relating thereto – schizophrenia and bipolar disorder.

95. It is not by stroke of luck that Zyprexa has been Lilly's largest selling drug for a number of years and has generated astounding blockbuster revenues for the drug company. For years, Zyprexa generated several billions of dollars of revenue for the company and was among the top ten best selling drugs in the world. In 2003, Zyprexa sales rose to $4.4 billion and assumed the rank of world's fifth best selling drug.

96. Rather, from the outset, Lilly recognized the promotion of Zyprexa's not medically accepted indications and not medically necessary uses as the key to Zyprexa's blockbuster success, i.e., promoting the use of Zyprexa to treat off-label demographics who present with symptoms akin to those exhibited by patients diagnosed with those exceedingly rare mental illnesses – depression, sleeplessness, agitation: 1) elderly LTC residents, 2) depressed and distracted adults who are not diagnosed with schizophrenia or bipolar disorder and 3) children with conditions such as ADHD, autism, mood disorders and disruptive children. Lilly devised this game plan despite its awareness of numerous serious treatment emergent side effects caused by Zyprexa including diabetes, hyperglycemia, extraordinary weight gain and metabolic syndrome, to name a few.

97. Indeed, Lilly funded calculated studies with methodologies intended to contrive positive clinical data about Zyprexa to ensure Zyprexa's numerous, dangerous and even deadly side effects were kept from public purview.

98. Lilly succeeded. Zyprexa's incredible revenues and sales ranking directly stems from the drug's dangerous overuse off-label that have not been found by the FDA or medical compendia to be safe or effective. This dangerous overuse is directly attributable to Lilly's illegal off-label promotional tactics.

99. Upon information and belief, based upon the foregoing, Lilly began planning its national, aggressive off-label marketing campaign for Zyprexa even before Zyprexa had received FDA approval. In this regard, Lilly's devised a strategy prior to Zyprexa's launch

to market the drug not only for use with elderly and children, but also for a constellation of broad symptoms in the broad realm of mood and thought disorders, a strategy that gave rise to an ongoing pattern of false and misleading conduct.

100. This conduct directly and proximately resulted in both the submissions of claims for not medically accepted indications and not medically necessary uses of Zyprexa to Medicaid, Medicare, VA and CHAMPUS/Tricare programs in California and throughout the country as well as adverse health effects among participants of those programs.

101. Through this planning Lilly funded clinical studies for Zyprexa, for on and off-label uses, which ultimately Lilly planned to be used by its sales representatives to promote Zyprexa. Indeed, Plaintiff-Relator was given such studies by Lilly with the expectation that she learn the details of the studies backwards and forwards and use the contrived results of the studies in promoting Zyprexa off-label.

102. Lilly furthered its illegal avaricious Zyprexa business plan by creating a deceptive and misleading marketing campaign to create a LTC market for Zyprexa, among other off-label markets. Lilly falsely touted Zyprexa's superior efficacy in treating the generic mood and behavioral symptoms of schizophrenia and bipolar disorder; symptoms that Lilly knew were also prolific in the elderly population.

103. The purpose of the deceptive scheme was to create the misimpression that geriatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category were Zyprexa candidates, thereby creating a broad, ill-defined market for Zyprexa in the elderly demographic.

104. Lilly tweaked the message slightly for its other sales divisions, such as its primary care physician sales force, to achieve the same impact - to create the misimpression that adult and pediatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category would benefit from being prescribed Zyprexa in increasing doses, thereby creating an across the board off-label for Zyprexa among patients who relied upon Medicaid, Medicare, the VA and/or CHAMPUS/Tricare to fund their necessary prescription drug needs.

A. Lilly's Calculated Training Of Zyprexa Sales Representatives to Successfully Market Zyprexa Off-Label to, *inter alia*, Medicaid/Medicare Beneficiaries

105. Lilly's scheme was highly successful. Data shows that well over half of all dollars spent on Zyprexa is spent on non-medically accepted or not medically necessary uses. Moreover, Zyprexa has been prescribed to more than 12 million people worldwide since the atypical antipsychotic's launch in 1996. Crucial to this Blockbuster success was Lilly's aggressive marketing of Zyprexa for elderly use through its LTC sales division, which consisted chiefly of exaggerating the drug's uses, while concealing its life-threatening side effects.

106. Lilly created complicated marketing structures that appeared independent from their proprietary of promotion forces.

107. Lilly sales representatives were expected in the course and scope of their employment to identify specific doctors (*i.e.* physicians who were already prescribing large volumes of Zyprexa or physicians whose antipsychotic "business" Lilly wanted to obtain) to recruit and communicate Lilly's interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Zyprexa often were given substantial funds by Lilly in the form of research grants, many unrestricted. These funds were in reality kickback paid to induce the physicians' use of Zyprexa.

108. Lilly engaged in this duplicitous conduct to create the false perception that respected physicians were using and investigating Zyprexa's efficacy in non-medically accepted and not medically necessary uses on their own initiative, and not as a result of Lilly's marketing activities. And in addition to providing free travel to resorts, free lodging and free meals, Lilly also paid these physicians to give talk segment medical education seminars, advisory boards, consultants meetings, speakers bureaus and similar events that favorably discussed not medically accepted and not medically necessary uses of Zyprexa.

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1) Promotion to the Elderly

109. The generic symptoms Lilly unlawfully promoted Zyprexa to treat mimicked those of dementia and/or Alzheimer's, including agitation, anxiety, and insomnia. By marketing the drug for the treatment of ***symptoms*** for which Zyprexa was not approved, Lilly violated strict FDA labeling regulations detailed *infra*.

110. Lilly encouraged use of Zyprexa in the elderly demographic to treat multiple symptoms that might be categorized as relating to dementia and/or Alzheimer's. To assist in these efforts, Lilly created patient profile detail aids whose focus was on "behavior treatment" such as agitation, suspiciousness, depressive mood, anxiety, and lack of concentration. By focusing on symptoms rather than the diagnoses of schizophrenia or bi-polar disorder, Lilly intended to overcome Zyprexa's lack of any FDA approved market for Zyprexa in the LTC demographic.

111. Lilly propagated the intentionally misleading message that Zyprexa was indicated for the treatment of dementia by directing its sales force to focus on behavioral and cognitive symptoms such as anxiety, depression, agitation during physician sales calls.

112. Among the most common, treatment-emergent adverse ***side effects*** of Zyprexa and the other atypical antipsychotics is ***somnolence***. Somnolence is defined as sleepiness, the state of feeling drowsy, ready to fall asleep. Within its drug class, Zyprexa is the most heavily sedating.

113. One approach Lilly devised for its LTC sales representatives was to market Zyprexa's somnolence side effects as method to reduce patient care hours by essentially chemically restraining demanding elderly patients.

114. Indeed, Lilly preyed upon the fact that providing care to elderly LTC residents who typically exhibit combative behavior and aggression is considerably stressful, frustrating and time consuming.

115. By way of example, Plaintiff-Relator and other Lilly LTC sales representatives were given studies by Lilly to distribute to LTC staff espousing ostensibly clinical evidence that elderly patients prescribed Zyprexa required fewer skilled nursing